

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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APOTEX, INC.,	)	
	)	
	)	
<i>Plaintiff</i>	)	
	)	CIVIL ACTION
v.	)	
	)	No. 2:06-cv-2768-MSG
CEPHALON, INC., <u>et al.</u>	)	
	)	
<i>Defendants</i>	)	
	)	

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**STIPULATIONS**

**I. The Parties and the Lawsuit**

1. Plaintiff Apotex Inc. ("Apotex") is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Dr., Weston, Ontario M9L 1T9.
2. Defendant Cephalon, Inc. ("Cephalon") is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.
3. On October 6, 1994 U.S. Patent Application No. 08/319,124 ("the '124 application") was filed at the United States Patent and Trademark Office ("PTO"). On April 8, 1997, the '124 application issued as U.S. Patent No. 5,618,845 ("the '845 patent") with six claims. The '845 patent is titled "Acetamide derivative having defined particle size," names as inventors Peter E. Grebow, Vincent Corvari and David Stong, and was assigned to Cephalon.
4. On April 1, 1999, U.S. Patent Application No. 09/285,166 ("the '166 application") was filed seeking a reissue of the '845 patent. On January 15, 2002, the '166 application issued as U.S. Reissue Patent No. 37,516 (the "RE '516 patent") with twenty-six claims. The RE '516 patent is titled "Acetamide derivative having defined particle size," names as inventors Peter E. Grebow, Vincent Corvari and David Stong, and was assigned to Cephalon.

5. On June 30, 1993, Cephalon filed an Investigational New Drug Application for Modafinil (CEP-1538) Tablets with the FDA. On December 26, 1996, Cephalon filed New Drug Application ("NDA"), No. 20-717, for Provigil®. The NDA was approved by the United States Food and Drug Administration ("FDA") on December 24, 1998. Cephalon began marketing Provigil® in February 1999.

6. The RE '516 patent was listed in the FDA's publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations." This publication is commonly known as the "Orange Book."

7. On March 30, 2005, Apotex filed an Abbreviated New Drug Application Number 77-667 (the "ANDA") seeking approval from the FDA for a generic version of Provigil®.

8. In its March 2005 ANDA, Apotex had a Paragraph III certification to the RE '516 patent. On March 9, 2006, Apotex changed its certification from a Paragraph III certification to a Paragraph IV certification and provided notice of its Paragraph IV certification to Cephalon.

9. On June 26, 2006 Apotex filed its original declaratory judgment complaint. (Dkt. No. 1). Apotex subsequently filed a first amended complaint (Dkt. No. 149) and a second amended complaint (Dkt. No. 195), which seek, *inter alia*, declaratory judgments that the RE '516 patent is not infringed, invalid and unenforceable.

10. On January 20, 2010 (Dkt. No. 196), this Court bifurcated Apotex's declaratory judgment claims on, *inter alia*, the RE '516 patent from its antitrust and other claims. On March 8, 2010 (Dkt. No. 211), Cephalon filed an answer to Apotex declaratory judgment claims on, *inter alia*, the RE '516 patent, and also asserted counterclaims seeking judgments that the '516 patent is infringed, valid, and enforceable.

11. In this matter, Cephalon has asserted infringement of claims 1-14 and 16 of the RE'516 patent against Apotex.

12. The specification of the U.S. Patent No. 5,843,347 (AI0000716-27) is an English translation of the specification of PCT Application Publication No. WO 94/21371 (AI 0000820-857).

## **II. Other Stipulated Facts**

13. Laboratoire L. Lafon ("Lafon") was a French company founded by Louis Lafon. Lafon was purchased by Cephalon on December 28, 2001 and is now known as Cephalon France.

14. The RE '516 patent specification refers to four "early" or "E" lots, namely E-A, E-B, E-C and E-D.

15. The RE '516 patent specification refers to two "late" or "L" lots, namely L-1 and L-2.

16. The lot numbers in the RE '516 patent correspond to Lafon lot numbers as follows:

'516 Patent Lot #	Lafon Lot Number
E-A	5/1939
E-B	5/2171
E-C	5/2236
E-D	002A
L-1	003
L-2	005

17. On January 20, 1993, Cephalon entered into Supply and License Agreements with Lafon.

18. Lot 003 was manufactured by Orsymonde, a company owned by Louis Lafon and his family, on March 18, 1993, and was used to manufacture a batch of tablets by Laboratoire Macors, a contract manufacturer to Lafon, on June 23, 1993.

19. On or about July 13, 1993, pursuant to the Supply Agreement, Lafon sent Cephalon 25 kg of Lot 003 modafinil API and 50,000 tablets from Macors lot M006. Cephalon received this API and tablets by July 23, 1993.

### **III. Trial Procedures**

20. Demonstrative exhibits need not be included in the parties' respective exhibit lists. The parties shall exchange final representations, on 8 ½" by 11" paper or electronically by PDF or PowerPoint, of demonstratives (subject only to addressing evidentiary objections or rulings) in hard copy form by 8:00 pm two calendar days before their intended use. For purposes of clarity, the foregoing exchange requirement does not apply to any demonstrative-type exhibits that are simply blow-ups, highlighted versions of, or call outs of other exhibits or testimony, or that are created by hand in the courtroom during trial.

21. Each party may use an exhibit that is listed on the other side's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to evidentiary objections. Each party reserves the right to object to the admission of evidence offered by the other party at the time such evidence is offered.

22. Each party shall provide the other party with notice at 8:00 p.m. two calendar days before each trial day of the witnesses that the party presenting its case expects to call (live and, if the Court permits the parties to use their trial presentation time to read or play their deposition designations, by deposition), the order in which they will be called, and the exhibits to be used on direct examination. For example, if a witness is scheduled to appear for his direct examination on a Wednesday, the preceding Monday at 8:00 p.m. would be the deadline for the disclosures.

Should a substantive trial event relating to a witness's testimony occur in the time period between the disclosures and the witness's trial appearance, a party has the right to supplement its disclosures in response to the substantive trial event, but is expected to do so as soon as reasonably possible and in any case no later than 7:00 p.m. the night before the witness's testimony.

23. Each party shall provide the other party with notice by 12:00 p.m. Monday, March 28, 2011 of all exhibits, deposition excerpts, and demonstratives that the party may use in opening statements.

Dated: March 27, 2011

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**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing document has been filed with the Court  
and is available for viewing and downloading from the Court's Electronic Case Filing System.

Date: March 28, 2011

/s/ Edward A. Diver

Edward A. Diver